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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,603	05/25/2006	Claude Lardy	MERCK-3173	4957
23599 7590 08/14/2008 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201				
EXAMINER HAYLIN, ROBERT H				
ART UNIT		PAPER NUMBER		
1626				
MAIL DATE		DELIVERY MODE		
08/14/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/580,603

Applicant(s)

LARDY ET AL.

Examiner

ROBERT HAVLIN

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☒ Claim(s) 2-14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☒ Information Disclosure Statement(s) (PTO/SG/08)
Paper No(s)/Mail Date 5/25/06
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of the claims: Claims 1-14 are currently pending.

Priority: This application is a 371 of PCT/EP04/14916 (11/17/2004), however, no priority was claimed in the application file AND no certified priority document is of record.

IDS: The IDS dated 5/25/06 was considered. Many of the references cited in the IDS were not provided and therefore were not considered.

Claim Rejections - 35 USC § 102

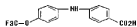
1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-10, 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoegberg et al. (WO 2003087045).

The reference teaches the compound



as a pharmaceutical agent for the treatment of diabetes.

This reads on the claims when R1 is -O-CF₃ at the 4-position and R2 is carboxyl at the 4-position.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoegberg et al. (WO 2003087045) in view of Yorek (Pubmed abstract of Free Radic Res. 2003 May;37(5):471-80).

The instant claims are for a method of using the pharmaceutical agents for: (11) the treatment of pathologies "characterized by an oxidative stress condition" and (14) a free radical scavenger.

Hoegberg teaches the use of the above cited compound for the treatment of a large number of disorders including diabetes.

Yorek teaches how patients with diabetes are known to have oxidative stress because of the increased presence of reactive oxygen species (free radicals).

The difference between the prior art and the claims is that Hoegberg does not specifically recite oxidative stress related disorders as being treated by their pharmaceuticals.

One of ordinary skill in the art would have found it obvious to use a pharmaceutical that treats diabetes to also use it to treat the oxidative stress disorders which arise from the same pathology. Therefore, because oxidative stress was known to result from diabetes one of ordinary skill in the art would know to use a diabetes pharmaceutical to treat the oxidative stress. Thus, the claims are obvious.

5. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hoegberg et al. (WO 2003087045) in view of Niemeijer-Kanters et al. (Pubmed abstract of Neth J Med. 2001 May;58(5):214-22).

The instant claims are for the preparation of a "hypotriglyceridaemiant medicament."

As discussed above, Hoegberg teaches the use of the same compounds for the treatment of diabetes.

Niemeijer-Kanters teaches how controlling lipid levels in diabetes is an important component treating diabetes, specifically, the control of triglyceride levels.

The difference between the instant claims and the prior art is Hoegberg teaches the treatment of diabetes while the claims are for treating triglyceride levels.

One of ordinary skill in the art would be aware of the close connection between diabetes and triglyceride levels as taught by Niemeijer. Therefore, it would have been obvious to one of skill in the art to use a known diabetes pharmaceutical to treat triglyceride levels, not only because of the teachings of Niemeijer, but also because triglycerides are well known stores of glucose. Therefore the claim is obvious.

Claim Objections

6. Claims 2-14 are objected for being dependent on a rejected base claim.
7. Claims 3, 5, 8, and 10 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. For

Art Unit: 1626

example, the dependent claims list "-F, -CI" as alternatives for R1, while the independent claim does not include these as possible definitions.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Havlin whose telephone number is (571) 272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert Havlin/
Robert Havlin, Ph.D.
Examiner
Art Unit 1626

/Kamal A Saeed, Ph.D./
Primary Examiner, Art Unit 1626